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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,880	05/14/2001	Gregory J. Riggins	00250.00003	6566

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	4

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,880	RIGGINS ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

1. The response filed October 30, 2002, paper no. 7, has been entered. However, upon further consideration, the prior Election/Restriction of paper no. 6 is withdrawn, and restriction and election are required as set forth below.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 7-12, drawn to methods of diagnosing glioblastoma by detecting nucleic acids, classified in class 435, subclass 6.

II. Claims 1-4 and 6-12, drawn to methods of diagnosing glioblastoma by detecting proteins, classified in class 435, subclass 7.1.

III. Claims 13-22, drawn to methods of delivering a reagent using an antibody, classified in class 424, subclasses 138.1, 174.1 and 178.1.

IV. Claims 23-29, drawn to methods of treating cancer with dendritic cells, classified in class 424, subclass 93.21.

V. Claims 30-34 and 36-47, drawn to methods of identifying anti-cancer drugs comprising detecting nucleic acids, classified in class 435, subclass 6.

VI. Claims 30-33 and 35-47, drawn to methods of identifying anti-cancer drugs comprising detecting proteins, classified in class 435, subclass 7.1.

3. It is pointed out that applicants have presented several claims in improper Markush format (see *Ex parte Markush*, 1925 C.D. 126 and *In re Weber*, 198 USPQ 328). Methods claims encompassing detection of both nucleic acids and polypeptides are improperly joined, as nucleic acids and polypeptides differs in structure and function

to such an extent that methods requiring their detection are considered separately patentable. Nucleic acids are composed of nucleotides and are detected by, e.g., hybridization with oligonucleotide probes, whereas polypeptides are composed of amino acids and are detected by, e.g., specific binding with antibodies. Therefore, the restriction has been set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species. Claims 1-4, 7-12, 30-33 and 36-47 have been included in multiple groups, and if elected, will be examined only as they read upon the invention of the elected group.

Upon election of any of Groups I-II or V-VI, Applicants are further required to amend the claims to set forth the elected inventive groups; otherwise these claims will be rejected as being in improper Markush format.

4. It is further noted that Groups I-VI each encompass **multiple, patentably distinct nucleic acids, proteins or antibodies** (and/or combinations thereof), and that election of a single molecule or of a single combination is required, as set forth below.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions I and III, I and IV, I and V, I and VI, II and III, II and IV, II and V, II and VI, III and IV, III and V, III and VI, IV and V, and IV and VI are patentably distinct methods having different objectives and effects and requiring the use of different reagents in different method steps. Invention I requires a step of comparing levels of nucleic acids in different tissue samples to achieve the objective of diagnosing glioblastoma. Invention II requires a step of comparing levels of proteins in different tissue samples to achieve the objective of diagnosing glioblastoma. Invention III

requires a step of contacting cells with an antibody conjugated with a reagent to achieve the objective of delivering a reagent to a glioblastoma. Invention IV requires a step of administering isolated cells to a human to achieve the objective of treating glioblastoma. Invention V requires steps of contacting a test compound with a cell and detecting nucleic acids to achieve the objective of identifying anti-cancer drugs. Invention VI requires steps of contacting a test compound with a cell and detecting proteins to achieve the objective of identifying anti-cancer drugs.

Invention I and II are patentably distinct methods. While the methods share a common objective, the methods require the use of different reagents in different method steps. Invention I requires the detection of nucleic acids, which are composed of nucleotides linked by phosphodiester bonds, and function in, e.g., hybridization or protein synthesis, while Invention II requires the detection of proteins, which are composed of amino acids linked by peptide bonds, and function in, e.g., enzymatic assays. Accordingly, the two methods require the detection of molecules that are structurally and functionally distinct from one another. Furthermore, detection of nucleic acids requires steps such as nucleic acid hybridization or amplification, while detection of proteins requires steps such as antibody binding. As Inventions I and II require the use of different reagents in different method steps to achieve the detection of structurally and functionally distinct target molecules, Inventions I and II are patentably distinct.

Invention V and VI are patentably distinct methods. While the methods share a common objective, the methods require the use of different reagents in different method

steps. Invention V requires the detection of nucleic acids, which are composed of nucleotides linked by phosphodiester bonds, and function in, e.g., hybridization or protein synthesis, while Invention VI requires the detection of proteins, which are composed of amino acids linked by peptide bonds, and function in, e.g., enzymatic assays. Accordingly, the two methods require the detection of molecules that are structurally and functionally distinct from one another. Furthermore, detection of nucleic acids requires steps such as nucleic acid hybridization or amplification, while detection of proteins requires steps such as antibody binding. As Inventions V and VI require the use of different reagents in different method steps to achieve the detection of structurally and functionally distinct target molecules, Inventions V and VI are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, and because Inventions I-VI require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper. Regarding Invention I as compared to Invention V, and Invention II as compared to Invention VI, it is particularly noted that while the Inventions share the same classification, the different objectives and method steps of Inventions I/V and II/VI necessitate different fields of search.

7. In addition to electing one of Groups I-VI, applicant is further required to elect a single patentably distinct gene, protein, or antibody, or, if applicable, a single combination of genes/proteins. Specifically:

a) Inventions I and IV encompass the detection or use of one of four distinct genes (see, e.g., claims 1 and 9-12 (re: Invention I); claims 23 and 26-29 (re: Invention IV));

b) Invention II encompasses the detection of one of four distinct proteins (see, e.g., claims 1 and 9-12);

c) Invention III encompasses the use of one of two distinct antibodies (see, e.g., claims 13-15):

d) Invention V encompasses the detection of one of four distinct genes (see, e.g., claim 30) as well as various combinations thereof (see, e.g., claims 41-43); and

e) Invention VI encompasses the detection of one of four distinct proteins (see, e.g., claim 30) as well as various combinations thereof (see, e.g., claims 41-43)

This is not an election of species. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Inventions I-VI encompass the detection/use of multiple nucleic acids/proteins/antibodies that are structurally and functionally distinct chemical compounds and are unrelated to one another. These molecules and methods requiring their detection/use are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. A reference against one would not be a reference against any other, and examination of claims encompassing detection/use of each gene/protein/antibody would require a different field of search. Absent evidence to the contrary, each such nucleic acid, protein, or antibody is presumed to represent an independent and distinct invention, subject to restriction pursuant to 35 U.S.C. 121 and 37 CFR 1.141. Further, regarding Inventions V-VI, each of the combinations encompassed by these Inventions has a different structure and a different combination of functional properties, and each combination would necessitate a different field of search. Accordingly, each combination is distinct from each other combination and from each individual gene/protein.

Applicant is advised that a reply to this requirement must include an **identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
January 13, 2003